## EnzymaticTherapy

NATURAL MEDICINES®

November 12, 2003

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

1630 W. W-1703

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE
Vitaline® Maximum Blue Label Formula	Maximum Blue provides high levels of antioxidants, which have been studied and found to promote neuronal growth and function.*	CLAIM REFERS  Vitamin A, Vitamin C, Vitamin D, Vitamin E, Thiamine, Riboflavin, Niacin, Vitamin B-6, Folic Acid, Vitamin B-12, Biotin, Pantothenic Acid, Calcium, Iodine, Magnesium, Zinc, Selenium, Copper, Manganese, Chromium, Molybdenum, Potassium, L-Lysine, Choline Bitartrate, Liver concentrate, Citrus Bioflavonoids,
		Inositol, PABA, Silicon, Boron, Vanadium

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: KLICILL

Title: Senior Vice President of Scientific Affairs

Date: \_\_ 11/12/03

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825 Challenger Drive Green Bay, WI 54311-8328

Ph. 920-469-1313

Fax: 888-570-6460

www enzy.com

Vitaline Maximum Blue Label Formula 1e